UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,376	07/09/2007	David G. Burton	8627-1391 (PA-5511-PCT/US	8852

48003 7590 03/02/2011

BRINKS HOFER GILSON & LIONE/CHICAGO/COOK
PO BOX 10395
CHICAGO, IL 60610

EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
03/02/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/593,376
Filing Date: July 09, 2007
Appellant(s): BURTON ET AL.

Richard E. Stanley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/28/2010 appealing from the Office action mailed 8/30/2010.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, 4, 12-16, 22, 24 and 25 are pending.

All pending claims have been rejected.

All pending claims are being appealed in this appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2003/0139762	Lee	7-2003
5,797,878	Bleam	8-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 12-16, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (United States Patent Application Publication Number 2003/0139762) in view of Bleam (United States Patent Number 5,797,878).

Lee discloses a dilation catheter comprising an elongate catheter body with a lumen in communication with an inflatable balloon (40), as best illustrated in Figure 1. The balloon (40) includes all of the structural components required by the claims, including a mid-section (44) that defines a "working length" between tapered proximal and distal regions (48 and 50). The tapered regions (48 and 50) provide smooth transitions from the working diameter in section (44) to the small diameter of the neck

regions (42 and 62). Each of the tapered regions (48 and 50) comprises a "taper-to-neck transition" and a "working length-to-taper transition", as labeled below:

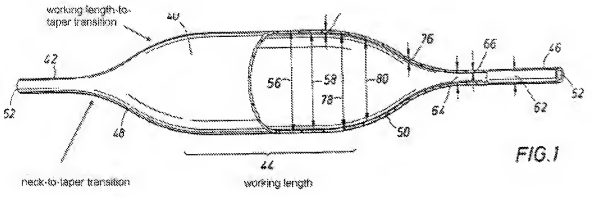

FIG. 1

Lee illustrates all of the transitions as having smooth, rounded edges and teaches that the tapered regions should be smooth in order to allow the balloon to traverse stenoses (paragraph 5). In paragraph 23, Lee further explains that the tapered regions (48 and 50) lie flattened when the balloon is in the deflated state and collapse to a low profile. The flattened tapers (48 and 50) provide the balloon with greater flexibility in the deflated state and lessen the resistance encountered by the balloon as it is maneuvered through tortuous vasculature (paragraph 23). Since the transitions are rounded, they could be described as having a transition radius.

In regards to claims 1, 3, 4, 22, 24, and 25: Lee discloses that the balloon is between 1.5 and 15 mm in diameter (paragraph 2), but fails to disclose the specific radii of the transitions when the balloon is in a deflated state as set forth in these claims.

Bleam discloses another balloon with a working length and proximal and distal tapers. Bleam seeks to minimizes the frictional forces during movement of the deflated balloon through vasculature (column 2, lines 12-22) and teaches that smaller taper angles and longer taper lengths can reduce these frictional forces (col. 2, lines 40-67). Although Bleam does not explicitly describe an increase of transition radii from the working length to tapered regions to achieve these results, Bleam does provide the teaching that the transition angles between working-length and tapered sections should be decreased in the deflated state in order to reduce frictional forces during delivery of the balloon through the vasculature.

Lee discloses that it is known to form balloons with rounded transitions between the working length and the tapered regions, and teaches that the tapers of the balloon should be substantially flat in the deflated state for easier maneuvering and less trauma to a patient's vasculature. Bleam is also directed toward this goal of forming a balloon that is more easily maneuvered during delivery and teaches that a balloon should have small angles in a transition zone so that the gradual increase in diameter provides a smoother profile. Therefore, one of ordinary skill in the art would have found it obvious to combine the teachings of Lee and Bleam to form a balloon with transition zones that are smooth, rounded, and provide a gradual change in diameter. The combination of Bleam's teachings of large transition angles with Lee's rounded transitions would provide the predictable result of forming a balloon with a very smooth profile in the deflated state so it is easily maneuvered through vessels and less traumatic to tissue.

Although the specific dimensions of the transition radii are not explicitly disclosed by Lee and Bleam, one of ordinary skill in the art would have found it obvious to form a balloon with a specific ratio of transition radius to working length diameter set forth in any of claims 1, 3, 4, 22, 24 and 25. Changing the radius of a rounded edge is within the level of ordinary skill in the art, and it is also well known that larger radii produce smoother profiles. A modification to the size of the transition radii merely involves the combination of a known balloon shape with a well known method of creating smooth edges in order to provide the predictable result of forming a balloon with a very smooth deflated profile. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 12-14: Bleam discloses the angles at the "taper-to-neck" and "working length-to-taper" transitions can be equivalent (col. 6, lines 57-65) and discloses that the balloon ends 22 and 24 are symmetrical (col. 6, lines 23-31). Therefore, it would have been further obvious to form transition zones to have equal radii.

Regarding claims 15 and 16: Lee discloses the proximal and distal tapers can be formed asymmetrically and the diameters along the taper can be either constant or varied (paragraph 31). As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide varying transitional radii amongst any of the four transition zones to accommodate the various taper diameters.

Regarding claim 22: Lee further discloses inserting a dilation catheter through a conduit, inflating the balloon, deflating the balloon, and applying a force to the catheter to remove the balloon (paragraphs 4 and 5).

(10) Response to Argument

In response to Applicant's arguments, the Examiner has admitted that Lee and Bleam do not disclose the specific dimensions of the balloon's transition radii and that the references do not explicitly discuss enlarging the radii of the balloon transitions. Although the references do not discuss specific characteristic of the transition radii between working length and tapered regions of a balloon, as set forth in Applicant's claims, the prior art considered as a whole teaches the general concepts of forming a balloon with smooth, gradual transition zones between a working length and proximal and distal tapered sections.

The declaration under 37 CFR 1.132 filed 8/12/2010 is insufficient to overcome the rejection of claims 1, 3, 4, 12-16, 22, 24, and 25 based upon the combination of Lee and Bleam, as set forth in the last Office action because:

Applicant's arguments with respect the manufacturing method and thickness of the walls of the balloon disclosed by Lee are considered to be irrelevant to the issue of patentability of the balloon geometry as claimed. It is the overall shape, or profile, of the balloon disclosed by Lee that is relied upon for the rejection. Therefore, any specific characteristics of the wall of the device are not germane to this rejection.

The Examiner disagrees with Applicant's suggestion that the rejection is based upon measurements from the drawings of Lee. Because Lee provides no dimensions related to the tapered regions or transition zones, Lee is relied upon for disclosing a known shape or profile of a balloon.

Applicant argues that the references relate only to different parts of the balloon and provide different solutions to the problem of forming a balloon that minimizes crossing forces. Applicant also argues that the teachings of Bleam are only related to the angle of the taper and therefore do not effect the transition radii. Examiner recognizes that the angle of the taper may not impact the transition radii. Lee discloses the general shape of a balloon that has a transition edge with a radius that provides a smooth shape. Lee teaches that the tapers of the balloon should be substantially flat in the deflated state for easier maneuvering and less trauma to a patient's vasculature. Bleam is relied upon for teaching that the transition from the tapered regions to the working length should be as gradual as possible to achieve a smooth deflated profile. Both Lee and Bleam are directed towards forming a balloon that is easily moved through tortuous vasculature in the deflated state. One of ordinary skill in the art at the time the invention was made would have been led to combine the teachings of these two references with common knowledge in the art to arrive at the claimed invention with a high expectation of success and predictable results of forming a balloon with a very smooth shape for traversing tortuous anatomy in the deflated state. Since it is well known to accomplish a change in the shape of a rounded edge by changing the size of

the corner's radius, it is considered to be within the level of ordinary skill in the art to form the modified Lee balloon with the specific radii set forth in the claims.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SARAH WEBB/
Examiner, Art Unit 3731

Conferees:

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

/Michael Phillips/ RQAS